K071274

3. 510(K) SUMMARY

1. Applicant/Sponsor: Gold Standard Orthopaedics, LLC.
   1226 Rowan St.
   Louisville, KY 40203

AUG 24 2007

2. Contact Person: David Baughman
   President
   David06@Baughmangroup.com
   Phone (502) 581-8770

3. Proprietary Name: GSO GS1 Spacer

4. Common Name: Vertebral Body Replacement

5. Classification Name: Spinal Intervertebral Body Fixation Orthosis
   (21 CFR 888.3060)

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   - Radiotransparent Open Implant (ROI) – LDR Spine USA (K043349)
   - CAS Spine Spacer System – EBI, L.P. (K042268)

7. Device Description:

   The GSO GS1 Spacer is a slightly curved, hollow spacer with pyramidal teeth on the superior and inferior ends to resist expulsion. The device contains openings to allow the surgeon to pack the device with bone graft (autograft or allograft) prior to insertion. Openings in the anterior-posterior direction permit bone growth through the device. The GSO GS1 Spacer is intended for use with supplemental internal fixation.

   The GSO GS1 Spacer is fabricated from medical grade titanium alloy.

8. Intended Use:

   The GSO GS1 Spacer is intended for use in the thoracolumbar spine (i.e., T1 - L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The GS1 Spine Spacer System is also indicated for treating fractures of the thoracic and lumbar spine. The GS1 Spine Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. Supplemental internal fixation is required to properly utilize this system.

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9. Summary of Technologies/Substantial Equivalence:

   The GSO GS1 Spacer has a similar design, is offered in similar sizes, is manufactured from the same material and has the same indications for use as the predicate CAS Spine Spacer System devices. Mechanical testing demonstrates that the GSO GS1 Spacer meets or exceeds the performance requirements published for the ROI Spacer. There are no significant differences between the GSO GS1 Spacer and the predicate devices that could affect the safety or efficacy of the device.

10. Non-Clinical Testing:

    Mechanical testing included static axial compression, dynamic compression, static torsion, dynamic torsion, and expulsion testing. Where applicable, this testing conformed to ASTM F2077. These tests demonstrate that the GS1 Spacer meets its functional requirements and is substantially equivalent to one of the predicate devices.

11. Clinical Testing:

    Clinical testing was not necessary to demonstrate substantial equivalence between the GSO GS1 Spacer and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gold Standards Orthopaedics, LLC
% Mr. David Baughman
President
1226 Rowan St.
Louisville, Kentucky 40203

AUG 24 2007

Re: K071274
Trade/Device Name: GSO GS1 Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: July 10, 2007
Received: July 12, 2007

Dear Mr. Baughman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Last Updated: Brandi Stuart – 7/9/07

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2. INDICATIONS FOR USE

510(k) Number (if known): N/A (unknown)

Device Name: GSO GS1 Spacer

Indications for Use:

The GSO GS1 Spacer is intended for use in the thoracolumbar spine (i.e., TI - L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The GS1 Spine Spacer System is also indicated for treating fractures of the thoracic and lumbar spine. The GS1 Spacer is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. Supplemental internal fixation is required to properly utilize this system.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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